UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,185	12/31/2003	George M. Halow	A-8636	5571

7590 08/11/2005

Jean A. Buttmi, Esq.
HOFFMAN, WASSON & GITLER, PC
Suite 522
2461 South Clark Street
Arlington, VA 22202

EXAMINER	
LEWIS, AMY A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,185	HALOW, GEORGE M.	
	Examiner	Art Unit	
	Amy A. Lewis	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/15/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Case

Claims 1-25 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 15-25 are indefinite because they are drawn to *both* a composition or a method of treatment, however they depend from claims directed to only one class.

Claims 15-25 are directed to "a method or composition." Due to the organization of the claim dependencies, claims 15, 16, 19, 22, and 23 will be examined as claims directed to a method of treatment, and claims 17, 18, 20, 21, 24, and 25 will be examined as claims directed to a composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by

Roblin, et al. "Use of polyethylene glycol 4000 in hepatic encephalopathy related to digestive hemorrages," *Gastroenterol Clin Biol* 1994 18(12): 1146.

Roblin teaches the treatment of hepatic encephalopathy with polyethylene glycol 4000 (English translation of the title; article in French).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2) Claims 1, 4, 19, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roblin, et al. "Use of polyethylene glycol 4000 in hepatic encephalopathy related to digestive hemorrages," *Gastroenterol Clin Biol* 1994 18(12): 1146 and Vicidomini F and Labruzzo F (EP 1230918 A2).

Roblin teaches the treatment of hepatic encephalopathy with polyethylene glycol (PEG) 4000 (title only). The reference does not teach lactulose for the treatment of hepatic encephalopathy.

Vicidomini teaches an aqueous enteroclysis solution containing, as an active ingredient, lactulose for the treatment of hepatic encephalopathy, particularly of porto-systemic encephalopathy (abstract). The reference teaches that the aqueous solution contains a quantity of disaccharide (i.e. lactulose) ranging from between 0.05 g/mL to 0.5 g/mL, and that the solution is prepared by adding the components directly to spring water, both of which are in crystalline form and soluble in water (paragraphs [16-17]), thus meeting the limitations that the composition be in powder form and free of added electrolytes. The reference does not teach PEG for the treatment of hepatic encephalopathy.

The following case law is believed to be relevant to the instant claim rejections:

In re Kerkhoven (205 USPQ 1069, CCPA 1980) states that "It is *prima facia* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose: the idea of combining them flows logically from their having been individually taught in the prior art." Therefore, it would have been obvious to the skilled artisan to combine polyethylene glycol and lactulose, motivated by their having been taught by the prior art to be useful in treating hepatic encephalopathy, consonant with the reasoning of the cited case law.

3) Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roblin, et al. "Use of polyethylene glycol 4000 in hepatic encephalopathy related to digestive hemorrages,"

Gastroenterol Clin Biol 1994 18(12): 1146 and Vicidomini F and Labruzzo F (EP 1230918 A2), as applied to claims 1, 4, 19, 22 and 23 above, and further in view of Pelham et al. (US 2005/0152989 A1).

Roblin teaches the treatment of hepatic encephalopathy with polyethylene glycol (PEG) 4000 (title only). The reference does not teach lactulose for the treatment of hepatic encephalopathy.

Vicidomini teaches an aqueous enteroclysis solution containing, as an active ingredient, lactulose for the treatment of hepatic encephalopathy, particularly of porto-systemic encephalopathy (abstract). The reference teaches that the aqueous solution contains a quantity of disaccharide (i.e. lactulose) ranging from between 0.05 g/mL to 0.5 g/mL, and that the solution is prepared by adding the components directly to spring water, both of which are in crystalline form and soluble in water (paragraphs [16-17]), thus meeting the limitations that the composition be in powder form (of instant claims 19-21) and free of added electrolytes (of instant claims 22-25). The dosage range of between 0.05 g/mL to 0.5 g/mL translates to a dosage of between 10-100g of lactulose, thus meeting the specific limitations of instant claims 8 and 13. The reference does not teach PEG for the treatment of hepatic encephalopathy.

Pelham et al. (US 2005/0152989) teaches a composition of laxitive and fiber for the treatment of irritable bowl syndrome, which includes constipation, containing lactulose and polyethylene glycol (PEG). See: abstract; paragraph [0004] and [0013]. The reference teaches that lactulose is a poorly absorbable disaccharide (i.e. fiber) (paragraph [0022]), and that PEG is an osmotic laxative which may be solid or liquid at room temp (see paragraphs [0023-0024]). The reference teaches dosages of PEG (see paragraph [0046 & 0048]) which overlap those of

instant claims 3, 7, 9, 12, and 14. The reference also teaches laxative to fiber ratios of 3:1 to 1:3 and 1:1, which overlap those of instant claims 5, 6, 10, and 11 (see paragraph [0031]).

The following case law is believed to be relevant to the instant claim rejections:

In re Kerkhoven (205 USPQ 1069, CCPA 1980) states that "It is *prima facia* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose: the idea of combining them flows logically from their having been individually taught in the prior art." Therefore, it would have been obvious to the skilled artisan to combine polyethylene glycol and lactulose, motivated by their having been taught by the prior art to be useful in treating hepatic encephalopathy and constipation, and with the specific formulation and dosage ranges for a composition containing PEG and lactulose taught by Pelham et al., consonant with the reasoning of the cited case law.

Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy A. Lewis
Patent Examiner
Art Unit 1614

Amy Lewis

Christopher Low
SPE
Art Unit 1614

Christopher Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600